PRACTITIONER TRAINING · MEDICAL DEVICE QUALITY

# US FDA QMSR (21 CFR Part 820) Training

Self-paced online training (video) · 14 modules · about 3.5 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Understand and meet the FDA Quality Management System Regulation, 21 CFR Part 820, which incorporates ISO 13485:2016 by reference and took effect on 2 February 2026, for devices sold in the United States.

## WHO IT IS FOR

Quality and regulatory affairs managers of medical device companies selling in the United States, QMS leads moving from the former Quality System Regulation, contract manufacturers and specification developers, and internal auditors of device QMS.

## WHAT YOU WILL LEARN

- Explain the QMSR, its scope and how it incorporates ISO 13485:2016 by reference
- Identify the FDA-specific requirements that apply alongside ISO 13485
- Map your existing QMS from the former Quality System Regulation to the QMSR
- Apply risk management across the QMS and the product life cycle
- Prepare records, complaint files and design documentation for FDA inspection
- Build a gap assessment and action plan for your own organisation

## MODULES (14)

1. Welcome: why the QMSR matters
2. From QSR to QMSR: why and who
3. Incorporation by reference
4. Management responsibility and the QMS
5. Risk management across the QMS
6. Resources, competence and infrastructure
7. Design and development controls
8. Purchasing and supplier controls
9. Production, validation and traceability
10. Records, complaints and labelling
11. Feedback, complaints and reporting
12. CAPA, audits and nonconforming product
13. How FDA inspects under the QMSR
14. Your gap assessment and action plan

### PRICE

**US$99 per learner**

Per learner, by team size

| | |
|---|---|
| 1–10 learners | **US$99** |
| 11–50 learners | **US$79** |
| 51–200 learners | **US$69** |

Excluding taxes.

### DURATION

About 6 hours in total (3½ hours of video)

### MODULES

14

### FORMAT

Self-paced online training (video)

### LANGUAGE

English, with captions

### ACCESS

12 months

### CERTIFICATE

Sterling Academy Certificate of Completion

Scan for the course page, prices and enrolment